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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,080	10/23/2003	Richard L. Apodaca	PRD0025NP	8314

27777 7590 09/14/2006

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EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/692,080

Applicant(s)

APODACA ET AL.

Examiner

Celia Chang

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1,7,8,14-23,29,30,42,44-46,48,49,54,63,64 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 63,64 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,42 and 54 is/are rejected.
- 7) ☐ Claim(s) 8,14-23,29,30,44-46,48 and 49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Applicant's election of Group I with modification to Q includes piperidine and pyrrolidine in the reply filed on July 3, 2006 is acknowledged. The modification is on the ground that the additional search should not place serious burden. This is not persuasive. However, in view of applicants' wish of not to file excessive divisionals, the Examiner will accept the modification. Therefore, groups I and II restriction has been withdrawn. The restriction of the remaining groups III-XIII are proper and maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-6, 9-13, 24-28, 31-41, 43, 47, 50-53, 55-62, 65 have been canceled.

Claims 1, 7-8, 14-23, 29-30, 42, 44-46, 48, 49, 54 are prosecuted. Claims 63, 64 and 66 are withdrawn.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a "composition" comprising a compound of formula I which is very confusing since the remaining claims 7-8, 14-23, 29-30, 42, 44-46, 48, 49, 54 are drawn to compound claims. If the base claim is a "composition" then all the dependent claims are improper because there is no compound in the base claim. The dependent claims must also be made "composition" of claim 1 containing a compound....etc. Since there is a claim 54 composition comprising a compound of claim 1, it is recommended that claim 1 be made into a compound claim.

3. Claims 1 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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It was noted that the substituents listed on page 3 of the July 3, 2006 amended claim 1 and 7, “wherein R1 and R2 are optionally and independently substituted.....” are not found in the specification. The set of substituents have been described on p. 19 of the specification being substituents of the Q moiety. The NR1R2 ring structure substituents only find antecedent basis on page 17, paragraph (g).

The mixing and matching of substituents for one Markush element with another Markush element is considered NEW MATTER. Removal of new matter is required. In re Russmussen 210 USPQ 325.

4. Claims 1, 42 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description, as well as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention or the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Description for the claimed scope of formula of “salt, ester, solvate or amide” is insufficient and ambiguous. It is noted that on pages 26-36 various protection of functional groups were described. No description for what kind of salt or the protected functional group compounds would have similar utility as the compounds of claim 1 or 40. Please note for proper Markush grouping, all the compounds within the Markush scope share substantial structural similarity which is responsible for the same utility (see MPRP 803.02). Nowhere in the specification described what salts, what ester or what amide would have the same utility as the formula I compounds. Further, no description as to what kind of solvate can be formed with the compounds and to have same utility. Absent of any description, one having ordinary skill is offered mere language rather than enablement for the compounds as well as their composition.

Please note that solvates are innate in nature. Without any indication or guidelines as to what solvents, what compound can form solvate, the specification offered mere language rather than enablement for the compounds as well as their composition.

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Further, the claims included  $p+q=4$  compounds with the enormous combination of L, Ra, R5, R3, R4. Absent of any description of the seven membered ring compounds (see CA140:375080 where delineation of all the compounds made by the instant application have been recited), the starting material and how to make such compounds, the mere language  $p+q$  is 4 offered no enablement to one for making and/or using such compounds or their composition. Ex parte Moersch 104 USPQ 122.

5. The request of rejoinder for claims 63, 64 and 66 cannot be made at this time. It has been stated in the restriction requirement that claims which can be rejoined must be free of 112 issues.

Claim 63, 64, 66 lacks written description and failed to comply with the enablement requirement.

The specification provided no information as to what is the nature of the binding between any of the claimed compound and the histamine H3 receptor. Please note that "binding" does not describe whether the interaction between the compound and the receptor is *agonistic* or *antagonistic*. Especially, only in vitro binding was described on pages 87-88.

It is well documented in the art that for histamine H3 receptor active compounds, those which binds agonistically increase slow-wave sleep while those which binds antagonistically increase wakefulness (see Leur et al. 1998 therapeutic potential..... recited on 1449, p.180) i.e. treating opposite sleep disorder. Some H3 agonists have been useful in treating air-way inflammation (see Leurs et al. 1996 medicinal chemistry.... Recited on 1449 p.156-158) while H3 antagonists are potentially useful in epilepsy.

The specification provided no description as to structural or functional analogue of the instant compounds with a known agonist or antagonist, nor did the specification provide any agonistic or antagonistic binding or in vivo data for treating any of the conditions as claimed.

Claims 63, 64 and 66 would not be rejoined but stayed withdrawn and the restriction is maintained.

6. Claims 8, 14-23, 29, 30, 44-46, 48, 49 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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The specific compounds are neither anticipated nor rendered obvious by the art of record.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Sept. 7, 2006

  
Celia Chang  
Primary Examiner  
Art Unit 1625